510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

FEB 14 2007

Date of Preparation: November 29th, 2006

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Device Information:

Trade Names:	Chiba, Chiba Special, Special Sprotte, Kit acc. Dr. Steinhoff, Initial Puncture needle/ cannula, Breast Localization cannula/ needle
Common Name:	Pajunks soft tissue biopsy, puncture and aspiration cannulas and needles
Classification Name:	Gastroenterology-urology biopsy instrument Handheld biopsy instrument
Classification Reference:	21 CFR § 876.1075, April 1st, 2006 21 CFR § 878.4800, April 1st 2006
Additional Classification:	Kit, Needle, Biopsy
Additional Classification Reference:	Gastroenterology-urology biopsy instrument.
Poposed Classification:	Regulatory Class II
Product Classification Code:	KNW
Additional Product Classification Code:	FCG
Classification Panel:	Gastroenterology/ Urology
Additional Review Advisory Committee:	General & Plastic Surgery
Predicate Devices:	1. **K980211 Manan MRI Chiba, spinal, breast localization etc.**

Indications for use

Breast localization cannulas/ needles

Pajunks breast localization cannulas/ needles can be used in Mammographic procedures to obtain breast lesion tissue.

Soft tissue puncture and aspiration kit acc. Steinhoff

Pajunks soft tissue puncture and aspiration Kit acc. Steinhoff is intended for use in puncturing and aspiring for soft tissue biopsy.

Soft tissue biopsy needle/ cannula, Soft tissue puncture cannula/ needle, Initial Puncture Cannula/ needle, Soft tissue aspiration cannula/ needle, Chiba needle for soft tissue biopsy, puncture and aspiration

Chiba Special tip grinding cannula/ needle for soft tissue biopsy, puncture and aspiration

Special Sprotte tip cannula/ needle for aspiration, puncture and biopsy

Pajunks soft tissue biopsy, puncture and aspiration cannulas and needles listed above are intended for obtaining biopsies from soft tissues, for use in puncturing and for aspiration. They are EO-sterilized, latex-free devices for single use.

It is not appropriate for bone biopsies.

Device Description

Soft Tissue Biopsy, Puncture and Aspiration Cannulas and Needles

The cannulas and needles consist of medical grade steel, plastic luer hub and stylet (stabilizing mandrin inside cannula). For safety reasons, the graduated puncture cannula also has an additional depthstop installed at the shaft of the cannula.

Aspiration puncture cannula type Chiba Special

The cannula Type Chiba Special has been developed by PAJUNK® with an approx. 1 cm matted finish of the cannula tip and three additional ring-markings.

Aspiration puncture cannula type Chiba with beveled tip

For safety reasons, the graduated puncture cannula/ needle has an additional depth-stop installed at the shaft. As a standard, the cannulas/ needles with beveled tip are normally equipped with a handle plate and a depth stop.

Initial puncture cannula

This universally usable puncture cannula/ needle made of high-grade stainless steel is suitable for all percutaneous punctures with guidance wires. It is available in a 2-parted and in a 3-parted version, with and without graduation. The outer cannula has a rounded, blunt tip, and it is designed to match the inside stylet-cannula.

Special puncture cannula with atraumatic Sprotte tip

This cannula with a Special Sprotte tip is intended for obtaining biopsies from soft tissues, for use in puncturing and for aspiration. It is an EO-sterilized, latex-free device for single use.

Interventinal micro cannula Chiba type

For better depth control, the interventional micro-cannula features graduated collars at intervals of 1 cm.

Aspiration-puncture cannula with injecting tube acc. Steinhoff

The puncture kit according Dr. Steinhoff contains a Chiba-type puncture cannula/ needle with a cannula rider and a flexible tube. The millimeter-precise introduction of the puncture needle by means of the cannula rider is facilitated with the aid of the centimeter-graduation and the corresponding markings at intervals of 5 mm. Thereby, the needle can be guided safely, without lacking the necessary flexibility.

Breast Localization cannulas

Pajunks breast localization cannulas can be used in Mammographic procedures to obtain breast lesion tissue.

Predicate Devices:

Predicate Device for Pajunks soft tissue biopsy and aspiration cannulas and needles are the cannulas and needles cleared for market by Manan in K980211. These devices have identical indications for use and the same technical specification in materials and grinding as Pajunks cannulas.

Pajunks Chiba cannulas/ needles are already cleared for market for a different intended use (anesthesia conduction, spinal and epidural) in K040965.

The detailed discussion of substantial eqivalence can be found in Section 12 of this submission.

Sterilization

Pajunks soft tissue biopsy and aspiration cannulas and needles are supplied packed in a blister as single-use, sterile, pyrogenfree and latex free disposable cannulas.

The contract sterilizer and the sterilizing process at Sterigenics is the same as that one used for all further Pajunk products already cleared for market in the USA. All cannulas are very similar in dimensions and materials.

Sterilization of Pajunks soft tissue biopsy and aspiration cannulas and needles at Sterigenics is being done according to a documented process. This **E**thylene **O**xide sterilization process is recurrently evaluated for suitability and effectiveness and the results are acceptable.

Sterilization of the Pajunks soft tissue biopsy and aspiration cannulas and needles is accomplished using Ethylene Oxide (EO) sterilization to a Sterility Assurance Level (SAL) of $< 10^{-6}$. After manufacture the cannulas are arranged in a foil bag which is sealed. EO sterilization is accomplished with exposure to 100% EO in accordance with AAMI/ISO 10993-7.

Packaging and Labeling

The cannulas and needles subject to this premarket notification are packed and labeled employing the same validations, in-process-controls, procedures and materials as Pajunks disposable anesthesia conducting cannulas/ needles already cleared for market.

A process descriptions for labeling and packaging can be found in section 13.0 of this submission.

Biocompatibility status

All materials employed in the manufacturing process that may come in contact with blood, tissue or fluids to be injected have been cleared in Pajunks former 510(k) applications. Therefore they are deemed to be biocompatible. Testing according to ISO 10993 has been conducted successfully employing cannulas/ needles that consists of identical materials.

Furthermore these materials are long term proven materials for the use with medical devices.

Standards

There are no special standards applicable for the cannulas and needles. Applicable sections of FDA´s GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS FOR BIOPSY DEVICES USED IN GASTROENTEROLOGY AND UROLOGY have been taken into regard.

A list of all standsrds applied as applicable as well as a declaration of conformity with this standards can be found in section 9.0 of this submission.

Conclusion:

The comparison between the predicate devices and the proposed device in section 12 of this submission demonstrates that the proposed device is safe and effective, as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH
% Christian Quass
Director Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen, Germany

FEB 14 2007

Re: K063697
Trade/Device Name: Soft Tissue Biopsy, Puncture and Aspiration Cannulas and Needles
Initial puncture cannula/needle
Special puncture cannula with atraumatic Sprotte tip
Aspiration puncture cannula type Chiba Special
Aspiration puncture cannula type Chiba with beveled tip
Interventional micro cannula Chiba type
Soft tissue puncture and aspiration kit acc. Steinhoff
Breast localization cannulas/needles
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: II
Product Code: KNW, FCG
Dated: December 9, 2006
Received: December 13, 2006

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

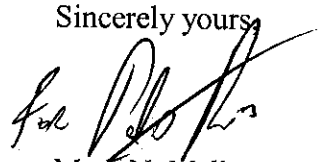
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for use

510(k) Number: **K063697**

Device Name: **Soft Tissue Biopsy, Puncture and Aspiration Cannulas and Needles**

Initial puncture cannula/ needle

Special puncture cannula with atraumatic Sprotte tip

Aspiration puncture cannula type Chiba Special

Aspiration puncture cannula type Chiba with beveled tip

Interventional micro cannula Chiba type

Indications for Use:

Pajunks soft tissue biopsy, puncture and aspiration cannulas and needles listed above are intended for obtaining biopsies from soft tissues, for use in puncturing and for aspiration.

They are not appropriate for bone biopsies.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K063697

Indications for use

510(k) Number: **K063697**

Device Name: **Soft tissue puncture and aspiration kit acc. Steinhoff**

Indications for Use:

Pajunks soft tissue puncture and aspiration Kit acc. Steinhoff is intended for use in puncturing and aspiring for soft tissue biopsy.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Indications for use

510(k) Number: **K063697**

Device Name: **Breast localization cannulas/ needles**

Indications for Use:

Pajunks breast localization cannulas/ needles can be used in Mammographic procedures to obtain breast lesion tissue.

Pajunks **Breast localization cannulas/ needles** are intended for diagnostic sampling of breast tissue during breast biopsy procedures. They are to be used for diagnostic purposes only and are not intended for therapeutic uses.

The **Breast localization cannulas/ needles** are indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

This device is not indicated for use under MR based imaging technologies, such as MRI.

Prescription Use____X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)